

**Remarks**

Claims 1, 2, 4 and 10 have been amended. The amendment to claim 1 finds support in the specification at, *inter alia*, page 8, lines 17 to 18 and 24 to 26, and at page 9, lines 24 to 26. The amendment to claim 2 deletes identification of the commercial sources of selected recited components. The amendment to claim 4 corrects a typographical error and the amendment to claim 10 is formalistic in nature. Applicants submit that no prohibited new matter has been introduced by any of the amendments.

**1. Claim Objections****A. Claim 4**

Claim 4 is objected to because of a typographical error in which “n” should be replaced by “in”.

Applicants have amended claim 4 to address the cited typographical error.

**B. Claim 10**

Claim 10 is objected to because the Examiner asserts that the space between the term “D” and “L” should be deleted “to more clearly convey that the D,L racemate is the intended member of the Markush group”.

Applicants have amended claim 10 to address the Examiner’s objection.

**2. Rejection under 35 U.S.C. 112, second paragraph**

Claims 2, 4-17 and 19-23 are rejected for the reasons provided on page 3 of the current Office Action. Specifically, the Examiner asserts that recitation of the commercial sources of the variously listed components renders the claims indefinite.

Applicants have amended claim 2 to delete any reference to the commercial sources in question, thereby effectively mooted this rejection.

**3. Rejection under 35 U.S.C. 103(a)****A. Galley in view of Martin**

Claims 1-7, 10, 13-18 and 21-23 are rejected as allegedly obvious over Galley (WO 91/11105) in view of Martin (U.S. Patent 5,652,274) for the reasons asserted on pages 5-9 of the

Office Action. At the bottom of page 8 of the Office Action, the Examiner appears to assert that Galley describes hydrated hydrogels as skin dressings in the form of two or more physically separated phases in which glucose oxidase is prevented from coming into contact with D-glucose until immediately prior to use.

Applicants submit that Galley does not disclose a hydrogel material. Rather, Galley describes material forms that may be powders, liquids, pastes or gels (see, *e.g.*, Galley at page 8, lines 17-24), none of which could be interpreted as teaching or suggesting a hydrating hydrogel material as recited in Applicants' claims. Further, Applicants submit that this particular passage from Galley is limited to "concentrated compositions" as can be seen by the introductory comment on page 7, line 30 of Galley. The phrase "concentrated compositions" has a particular meaning as used by Galley such that any physical separation of glucose oxidase from D-glucose is described only in the context of concentrated solutions such as double layered tablets, which are dissolved prior to use.

The only disclosure in Galley of a skin dressing is on page 11, under item g, and is in the context of a "preserved composition" in active form, which is not a concentrated composition. Accordingly, Applicants submit that there is no disclosure of physical separation in the form of a skin dressing, and thus it is simply not the case that Galley teaches this structure.

An essential feature of the physical separation of glucose oxidase and D-glucose in Galley is that these components are brought together into an intimate admixture prior to use. This essential feature is acknowledged by the Examiner in the Office Action and the aforementioned section of Galley at page 8, lines 17 to 24 is a good example of this teaching. Applicants therefore submit that the physical separation described in Galley is only intended for the storage of the compositions so that premature and undesired interaction between the glucose oxidase and the D-glucose does not occur.

Applicants' independent claim 1 requires that the physical separation of the glucose and the enzyme be maintained during use when in place on the skin of a human or animal body. In view of the clear teaching of Galley of bringing these components together into an intimate admixture, Applicants submit that Galley directly teaches away from Applicants' claimed invention. Accordingly, a person of ordinary skill in the art would never arrive at an embodiment of Applicants' claimed invention in view of Galley because there would be no

rationale for doing so. Martin, which is relied upon by the Examiner for teaching the presence of lactate ions in wound healing compositions, cannot remedy the deficiencies present in Galley. Therefore, Martin alone or in combination with Galley does not render Applicants' claims obvious. Applicants respectfully request that this rejection be withdrawn.

**B. Galley in view of Martin and further in view of Munro**

Claims 1, 6, 8, 9 and 19 are rejected as allegedly obvious over Galley in view of Martin and further in view of Munro (US 2002/0037270) for the reasons asserted on pages 10-11 of the Office Action. The Examiner acknowledges that neither Galley nor Martin teaches the use of polyAMPS as the hydrophilic polymer or the amount of hydrophilic polymer in the hydrogels and appears to rely on Munro for these teachings.

Applicants submit that Munro cannot remedy the deficiencies present in Galley and Martin as discussed in section 3A above. Therefore, Munro alone or in combination with Galley and/or Martin does not render Applicants' claims obvious. Applicants respectfully request that this rejection be withdrawn.

**C. Galley in view of Martin and further in view of Barrows**

Claims 1, 11, 12 and 20 are rejected as allegedly obvious over Galley in view of Martin and further in view of Barrows (US Patent 5,372,802) for the reasons asserted on pages 12-13 of the Office Action. The Examiner acknowledges that neither Galley nor Martin teach the use of zinc ions in the described compositions and appears to rely on Barrows for these teachings.

Applicants submit that Barrows cannot remedy the deficiencies present in Galley and Martin. Therefore, Barrows alone or in combination with Galley and/or Martin does not render Applicants' claims obvious. Applicants respectfully request that this rejection be withdrawn.

**D. Abraham**

Claims 1-4, 6, 15-17 and 23 are rejected as allegedly obvious over Abraham (WO 97/02811) for the reasons asserted on pages 14-15 of the Office Action. The Examiner asserts that Abraham discloses a hydrogel patch comprising an electrolyte solution and an enzyme capable of metabolizing glucose into hydrogen peroxide. The Examiner acknowledges that Abraham does not teach that the patch itself carries a supply of glucose, but asserts that one of ordinary skill in the art would be motivated to add a supply of glucose to the described patch to

provide a positive control for calibration purposes.

Applicants submit that a person of ordinary skill in the art wishing to calibrate the dressings would not be motivated to introduce a supply of glucose into the dressing itself. If calibration were the desired objective, then the skilled person would instead place the dressing in contact with a surface containing a known concentration of glucose. Abraham operates by diffusion of glucose from an outside source into the dressing. Calibration would therefore have to be carried out in this manner – *i.e.*, by introducing a known concentration of glucose **from an outside source**.

The Examiner appears to be suggesting that instead, calibration would be carried out in a completely different manner to which the patch would be operated in practice – *i.e.*, by introducing glucose into the dressing from the very beginning. There is no basis for assuming this mechanism of glucose introduction, and Applicants submit that it makes no technical sense.

In addition, Applicants' claimed invention as amended requires the presence of two separate and distinct components in the skin dressing. This feature is entirely absent from Abraham. To adapt Abraham in a fundamental manner by requiring a separate component comprising glucose would be antithetical to the teaching of Abraham, which requires a glucose measuring dressing. Applicants' claimed invention relates to a skin dressing located on the skin of a human or an animal. To introduce a layer comprising glucose between the enzyme containing component and the skin would render measurement of glucose levels in the skin impossible. A person of ordinary skill in the art would have no rationale for so modifying Abraham.

For at least the above reasons, Applicants submit that Abraham does not render Applicants' claimed invention obvious and respectfully request that this rejection be withdrawn.

#### **4. Statutory Double Patenting under 35 U.S.C. 101**

Claims 1-23 of the subject application are provisionally rejected as claiming the same invention as claims 1-23 of copending Application No. 10/044,715.

Applicants submit that the claims as amended in the subject application do not claim the same invention as recited in claims 1-23 of Application No. 10/044,715. Accordingly, Applicants respectfully request that this rejection be withdrawn.

**5. Provisional Obviousness-Type Double Patenting**

A. Application No. 10/512,440 (optionally in view of Martin)

Claims 1-23 of the subject application are provisionally rejected as obvious over claims 2, 5-7, 21, 22, 24, 25 and 30 of copending Application No. 10/512,440, optionally in view of Martin.

Applicants request that the Examiner hold this rejection in abeyance until allowable claims have been identified.

B. Application No. 10/587,547

Claims 1-23 of the subject application are provisionally rejected as obvious over claims 1-15 of copending Application No. 10/587,547.

Applicants request that the Examiner hold this rejection in abeyance until allowable claims have been identified.

**6. Conclusion**

Applicants respectfully request allowance of the pending claims in view of the above amendments and remarks. If helpful to further prosecution of the subject application, the Examiner is invited to telephone the undersigned.

If there are any fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 50-310. If a fee is required for an extension of time under 37 C.F.R. 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account.

Dated: **July 6, 2009**

Morgan, Lewis & Bockius LLP

Customer No. **09629**

1111 Pennsylvania Avenue, N.W.

Washington, D.C. 20004

Ph: 202-739-3000

Fax: 202-739-3001

Respectfully submitted,

**Morgan, Lewis & Bockius LLP**

/Gregory T. Lowen/

Gregory T. Lowen, Ph.D.

Registration No. 46,882

Direct: 202-739-5915